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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte STUART GREENHALGH, KENNETH CHARLES SYMES, YVONNE ARMITAGE, JONATHAN HUGHES, and GARY RICHARDSON

> Appeal 2011-003553 Application 10/580,447 Technology Center 1600

Before DEMETRA J. MILLS, JEFFREY N. FREDMAN, and STEPHEN WALSH, Administrative Patent Judges.

FREDMAN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a process for preparing a polymer which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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Statement of the Case

Background

The Specification teaches "a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtainable from a biocatalytic or a fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation broth . . . wherein there is substantially no removal of the cellular material and/or components of the fermentation broth from the ethylenically unsaturated-monomer" (Spec. 7, II. 19-27).

The Claims

Claims 1-12 and 14-18 are on appeal. Claim 1 is representative and reads as follows:

1. A process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtained from a biocatalysed reaction or a fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation broth, forming the polymer by polymerising the ethylenically unsaturated monomer or a monomer mixture comprising the ethylenically unsaturated monomer and cellular material and/or components of a fermentation broth in the presence of a redox and/or thermal initiator and the formed polymer exhibits an intrinsic viscosity of at least 3 dl/g measured using a suspended level viscometer in 1 M sodium chloride at 25°C.

The issue

The Examiner rejected claims 1-12 and 14-18 under 35 U.S.C. § 103(a) as anticipated by Yamada, ¹ Seki, ² and Leonova³ (Ans. 3-8).

The Examiner finds that Yamada teaches "preparing an acrylamide (such as methacrylamide, an ethylenically unsaturated monomer) in which the monomer is obtained from a biocatalysed reaction or fermentation process wherein the substrate (a nitrile such as methacrylonitrile) is contacted by a biocatalyst that comprises a microorganism or cellular material and thereby converted into the monomer" (Ans. 6). The Examiner finds that "Seki teaches that polymerization of a solution of acrylamide (an ethylenically unsaturated monomer) will occur under many conditions, such as in the presence of iron" (Ans. 6).

The Examiner finds that it obvious "to modify the teachings of Yamada in the course of routine experimentation such that the process would result in the polymerization discussed by Seki" (Ans. 7). Specifically, the Examiner finds that "it is either inherent to the teachings of Yamada, or it would occur during routine optimization and experimentation, that polymerization of the monomer in solution, such as in the fermentation broth, would occur" (Ans. 7).

Appellants contend that "Yamada separates the monomer from cellular and/or components of fermentation before polymerization." (App.

¹ Yamada et al., US 5,334,519, issued Aug. 2, 1994.

² Seki et al., US 5,352,828, issued Oct. 4, 1994.

³ Leonova et al., Nitrile Hydratase of <u>Rhodococcus</u>, 88 APPLIED BIOCHEMISTRY AND BIOTECHNOLOGY 231-241 (2000).

Br. 4). Appellants contend that Yamada teaches that "No polymerization takes place as the monomer is produced in 100% yield" (App. Br. 5).

Appellants contend that the "use of Seki's teachings by examiner that polymerization was likely to occur in a concentrated monomer mixture and thus could have occurred in the highly concentrated monomer mixture of Yamada as it contained debris from the fermentation process is at a minimum speculative and ignores the teachings of Yamada as a whole" (App. Br. 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that Yamada, Seki, and Leonova render claim I obvious?

Findings of Fact

- 1. The Specification teaches that "the term biocatalyst refers to microbial cells and cellular material as described here and to any other form of biocatalyst that is known that constitutes an enzyme and any associated cellular material present with the enzyme that may or may not be required to allow biocatalytic activity" (Spec. 8, Il. 20-23).
- The Specification teaches that "[p]articularly preferred microorganisms are those that can produce nitrile hydratase suitable for converting (meth) acrylonitrile to (meth) acrylamide" (Spec. 10, ll. 24-26).
- The Specification teaches that "preferably the ethylenically unsaturated monomer is acrylamide or methacrylamide. Other preferred monomers include . . . (meth)acrylic acid" (Spec. 12, 18-20).

- 4. The Specification teaches that "polymerisation initiators are introduced into the monomer or mixture of monomers to initiate polymerisation. Desirably this may be achieved by the use of redox initiators and/or thermal initiators" (Spec. 14, Il. 15-18).
- 5. Yamada teaches that in "a 1-liter Sakaguchi flask was placed 400 ml of a culture medium comprising the aforementioned culture medium C containing $CoCl_2$ and crotonamide added thereto, respectively, in a proportion of 0.01 g and 2 g per liter of the medium, and the mixture was cultured on a shaking apparatus at 28° C" (Yamada, col. 11, ll. 16-22).
- Yamada teaches that the "bacterial cells were collected by centrifuging the culture medium under 12,000 g for 15 minutes with a centrifugal separator" (Yamada, col. 11, ll. 27-29).
 - Yamada teaches that

suspension of the bacterial cells (corresponding to 4.66 mg of the dry cells) obtained in Example 2 was added to 4 ml of the reaction solution containing 10 mM of a potassium phosphate buffer (pH 8.0) and 3 M of methacrylonitrile, and the reaction was conducted at 25° C. with adding 3 M of methacrylonitrile to the reaction solution after 1 hour and 3 hours from the initiation of the reaction, respectively. After 12 hours from the initiation of the reaction, 9 M of methacrylamide was produced with a 100% conversion

(Yamada, col. 12, ll. 17-26).

8. Yamada teaches that the "reaction solution was diluted with water, and the bacterial cells were removed by centrifugal treatment (under 12,000 g for 15 minutes). The cell-free solution was concentrated on a rotary evaporator and crystallized. Then the crystals were dissolved in and

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recrystallized from water to obtain the crystals of methacrylamide" (Yamada. col. 12, II. 34-40).

- 9. Seki teaches that "as in the case of many other unsaturated monomers, acrylamide is apt to cause polymerization not only by its exposure to light or heat but also by its contact with an iron surface, and such properties cannot be altered by improving purity of its aqueous solution" (Seki, col. 1, II. 45-49)
- Leonova teaches that "[n]itrile hydratase (NHase) is a microbial enzyme catalyzing hydration of nitriles to the corresponding amides" (Leonova 231).

Principles of Law

An invention

composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.... [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007).

"Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *MEHL/Biophile Int'l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (quoting In re Oelrich, 666 F.2d 578, 581 (CCPA 1981)).

Analysis

The Examiner has provided no reason why the ordinary artisan would have chosen to polymerize the material in a mixture with either cellular material and/or fermentation broth components as required by claim 1. Instead, the Examiner contends that it is either inherent or the result of routine optimization (see Ans. 7).

We are not persuaded. We agree with Appellants that it is entirely speculative whether Yamada's methacrylamide monomers polymerize in the reaction mixture which contains cellular material (see, e.g., App. Br. 7). The Examiner has provided no evidence to establish that polymerization of the polyacrylamide necessarily occurs in the process of Yamada. Appellants reasonably point to Yamada's statement that "9 M of methacrylamide was produced with a 100% conversion" (Yamada, col. 12, ll. 25-26; FF 7) as demonstrating that if 100% of the product was the monomer, then by necessity, none of the monomer was converted into polymer (see App. Br. 5).

We also agree that there is no evidence that routine experimentation would have suggested forming the polymer in a mixture with either cellular material and/or fermentation broth components as required by claim 1. While the discovery of an optimum value of a variable in a known process is normally obvious (See In re Aller, 220 F.2d 454, 456 (CCPA 1955); there is an exception to this general rule, where the parameter optimized was not recognized to be a result effective variable. See In re Antonie, 559 F.2d 618, 621 (CCPA 1977). In this case, the Examiner has not demonstrated that the

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solution in which polymerization was to occur was a result effective variable.

Conclusion of Law

The evidence of record does not support the Examiner's finding that Yamada, Seki, and Leonova render claim 1 obvious.

CONCLUSION

In summary, we reverse the rejection of claims 1-12 and 14-18 under 35 U.S.C. § 103(a) as anticipated by Yamada, Seki, and Leonova.

REVERSED

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